

Regulation 61-97

Standards for Licensing Renal Dialysis Facilities

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PART 1 Administration

CHAPTER 1 Definitions and Interpretations

SECTION 101. Definitions

For the purpose of these standards, the following definitions shall apply:

A.Continuous Ambulatory Peritoneal Dialysis: A continuous manual exchange of dialysate into and from the peritoneal cavity (usually every four to six hours).

B.Continuous Cycling Peritoneal Dialysis: The use of a machine to warm and cycle the dialysate in and out of the peritoneal cavity (usually every four hours).

C.Dialysis: A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane.

D.Dietitian: A person who is registered by the Commission on Dietetic Registration.

E.End-Stage Renal Disease (ESRD): That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

F.ESRD Service: The type of care or services furnished to an ESRD patient. Such types of care are: transplantation service, dialysis service, self-dialysis and home dialysis training.

G.Home Dialysis: Dialysis performed by a patient at home who has completed a course in self-dialysis or home dialysis.

H.Inpatient Dialysis: Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital.

I. Licensed Capacity: The number of dialysis stations that the center or facility is authorized to operate to include chronic hemodialysis and home hemodialysis training stations.

J. Licensed Practical Nurse: Person licensed by the South Carolina State Board of Nursing as a licensed practical nurse.

K.Licensee: The individual, agency, group or corporation in which the ultimate responsibility and authority for the conduct of the renal dialysis facility is vested.

L.Licensing Agency: The Department of Health and Environmental Control.

M. Outpatient Dialysis: Dialysis furnished on an outpatient basis at a renal dialysis center or facility. Outpatient dialysis includes staff-assisted dialysis and self-dialysis.

N.Patient: A person admitted to and receiving care in a facility.

O.Patient Care Technician: A non-licensed person who provides direct patient care.

P. Registered Nurse: Person licensed by the South Carolina State Board of Nursing as a registered nurse.

Q.Renal Dialysis Facility: An outpatient facility which offers staff assisted dialysis or training and support services for self-dialysis to end-stage renal disease patients. A facility may be composed of one or more fixed buildings, mobile units, or a combination.

R.Self-Dialysis and Home Dialysis Training: A program that trains ESRD patients to perform self-dialysis or home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis.

S. Self-Dialysis Unit: A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and furnishes self-dialysis services.

T.Social Worker: A person licensed as a social worker by the South Carolina Board of Social Work Examiners.

U.Staff-Assisted Dialysis: Dialysis performed by qualified staff of the center or facility.

SECTION 102. Interpretations

A.Except as outlined in B, below, no person, partnership, corporation, private or public organization, political subdivision or other governmental agency shall establish, conduct or maintain a renal dialysis facility without first obtaining a license from the Department.

B.A renal dialysis facility license shall not be required for, nor shall such a license be issued to:

1. Facilities operated by the federal government.

2. Renal dialysis services provided in licensed hospitals (such services remain within the purview of R.61-16).

C.A license is issued pursuant to the provision of Sections 44-39-40 through 44-39-80 of the South Carolina Code of Laws of 1976, as amended, and the standards promulgated thereunder and shall be posted in a conspicuous place in a public lobby or waiting room. The issuance of a license does not guarantee adequacy of individual care, treatment, personal safety, fire safety or the well-being of any occupant of a facility. A license is not assignable or transferable and is subject to revocation by the Department for failure to comply with the laws and standards of the State of South Carolina.

D.Any renal dialysis facility which is in operation at the time of promulgation of any applicable rules or regulations shall be given a reasonable time, not to exceed one year from date of such promulgation, within which to comply with such rules and regulations.

E.Effective Date and Term of License: A license shall be effective for a 12-month period following the date of issue and shall expire one year following such date; however, a facility that has not been inspected during that year may continue to operate under its existing license until an inspection is made.

F. Separate Licenses: Separate licenses are required for facilities not maintained on the same premises. Separate licenses may be issued for facilities maintained in separate buildings on the same premises.

G.Licensing Fees: Each applicant shall pay an annual license fee prior to issuance of the license. The annual fee shall be two hundred dollars for the first ten stations and twenty dollars for each additional station.

H.Inspections: Each facility submitting an application for licensing or re-licensing shall be inspected prior to initial licensure and at least annually by authorized representatives of the Department. All licensed and prospective licensed facilities are subject to inspection at any time. All facilities to which these requirements apply shall permit entrance to all properties and access to every area, object and records and reports by representatives of the Department.

I. Initial License: A new facility, or one that has not been continuously licensed under these or prior standards, shall not provide renal dialysis services until it has been issued an initial license. Appendix A sets forth the prerequisites for initial license.

J. Noncompliance: When noncompliances with the Licensing Standards are detected, the applicant or licensee will be notified of the violations and at the same time requested to provide information as to how and when such items will be corrected. If an item of noncompliance is of a serious nature and is not promptly corrected, a penalty may be invoked or a license may be denied, suspended or revoked.

K.Exceptions to Licensing Standards: The Department reserves the right to make exceptions to these standards where it is determined that the health and welfare of the community require the services of the facility and that the exception, as granted, will have no significant impact on the safety, security or welfare of the facility's occupants.

L.Change of License: A facility shall request issuance of an amended license, by application to the Department, prior to any of the following circumstances:

1. Change of ownership by purchase or lease.
2. Change of facility's name or address.
3. Addition of a renal dialysis station or any part thereof.

SECTION 103. Penalties

Facilities shall be subject to a penalty for violating licensing regulations (Sections 44-39-40 through 44-39-80 and 44-7-320 of the South Carolina Code of Laws of 1976, as amended). When upon inspection or investigation the Department determines that a facility is in violation of any statutory provision, rule or regulation relating to the operation or maintenance of such facility except with respect to violations determined to have only a minimal relationship to health or safety, the following conditions apply:

A.Class I violations are those which the Department determines present an imminent danger to the patients of the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition, one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

B.Class II violations are those other than Class I violations, which the Department determines have a direct or immediate relationship to the health, safety or security of the facility's patients. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

C.Class III violations are those which are not classified as serious in these regulations or those which are against the best practices as interpreted by the Department. The citation of a Class III violation shall specify

the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

D. Class I and II violations are indicated by notation after each applicable section, e.g., (I) or (II). Violations of sections which are not annotated in that manner will be considered as Class III violations. As provided in Section 44-7-320 of the Code, the Department may deny, suspend, or revoke licenses or assess a monetary penalty for violations of provisions of law or departmental regulations. The Department shall exercise discretion in arriving at its decision to take any of these actions. The department will consider the following factors: specific conditions and their impact or potential impact on health, safety or welfare; efforts by the facility to correct; overall conditions; history of compliance; any other pertinent conditions. If a decision is made to assess monetary penalties, the following schedule will be used as a guide to determine the dollar amount.

**Frequency of
violation of
standard
within
a 24-month period:**

MONETARY PENALTY RANGES

FREQUENCY	CLASS I	CLASS II	CLASS III
1 st	\$ 200 - 1000	\$ 100 - 500	\$ 0
2 nd	500 - 2000	200 - 1000	100 - 500
3 rd	1000 - 5000	500 - 2000	200 - 1000
4 th	5000	1000 - 5000	500 - 2000
5 th	5000	5000	1000 - 5000
6 th and more	5000	5000	5000

CHAPTER 2 Licensing Procedures

SECTION 201. Application

A. Applicants for a license shall file applications under oath annually with the Department upon forms provided by the Department, and shall pay an annual license fee. The application shall set forth the following:

1. Name, address, and telephone number of facility;
2. Name and address of licensee;
3. Names of all parties with at least five percent ownership;
4. Names of operator(s) and/or governing authority;
5. Name of chief executive officer;

6. Numerical composition of medical and support staff;
7. Name of director of nursing services;
8. Number of renal dialysis stations;
9. Description of arrangements for emergency transportation of patients from the facility;
10. Name of hospital(s) with which a transfer agreement has been made, if applicable.

B. The governing authority shall file application for a license for a new facility or for the renewal of a license for an existing facility. Applications for a new facility or additional stations shall be submitted at least 30 days prior to opening.

SECTION 202. Requirements for Issuance of License

A. Upon receipt of an application for a license from a facility never before licensed, a representative of the Department shall make an inspection of that facility.

B. When it is determined that the facility is in compliance with the requirements of these standards, and a properly completed application and licensing fee have been received by the Department, a license shall be issued.

C. No proposed facility shall be named nor may any existing facility have its name changed to the same or similar name as a facility licensed in the State. If it is part of a "chain operation" it shall then have the area in which it is located as part of its name.

SECTION 203. Termination of License

A license is not assignable or transferable and is subject to revocation at any time by the Department for failure to comply with laws and standards of the State of South Carolina. When a licensed facility ceases operation, the license shall be returned to the Department within 10 days.

CHAPTER 3 Governing Authority and Management

SECTION 301. General

Every facility shall be organized, equipped, manned and administered to provide adequate care for each person admitted.

SECTION 302. Governing Authority

A. The governing board, or the owner, or the person or persons designated by the owner as the governing authority shall be the supreme authority responsible for the management control of the facility and shall not:

1. Permit, aid or abet the commission of any unlawful act relating to the securing of a certificate of need or the operation of the facility; and/or

2. With the exception of abusive or disruptive patients, refuse to admit and treat, on the basis of medical need, alcohol and substance abusers, alcoholics, and mentally ill or persons with intellectual disability solely because of the alcoholism, mental illness or intellectual disability.

B.A written set of bylaws or other appropriate policies and procedures for operation of the facility shall be formulated by the governing authority. These shall: (II)

1. State the purpose of the facility;

2. Specify by name the person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the governing authority for holding such individual responsible;

3. Provide for at least annual meetings of the governing authority;

4. Provide for a policies and procedures manual which is designed to ensure professional and safe care for the patients to include but not limited to:

a. Admission criteria;

b. Rights and responsibilities of patients;

c. Patient grievance procedures;

d. Contamination prevention procedures;

e. Personnel training requirements;

f. Reuse of "kidney".

5. Provide for annual reviews and evaluations of the facility's policies, procedures, management and operation.

6. Provide for a facility-wide quality assurance program to evaluate the provision of patient care. The program shall have a written plan of implementation and be continuous with annual reviews.

SECTION 303. Administrator

The full-time administrator shall be selected by the governing authority and shall be responsible for the management and administration of the facility and shall see that the bylaws and amendments thereto are complied with. The Director of Nursing may serve as the administrator. Any change in the position of the administrator shall be reported immediately by the governing authority to the Department in writing. An individual shall be appointed to act in the absence of the administrator. The administrator must hold at least a baccalaureate degree or have a minimum of an associate degree in a health-related field with at least two years experience in ESRD within the past five years. (II)

SECTION 304. Administrative Records

The following essential documents and references shall be on file in the administrative office of the facility:

A.Appropriate documents showing control and ownership;

- B. Bylaws, policies and procedures of the governing authority;
- C. Minutes of the governing authority meeting if applicable;
- D. Minutes of the facility's professional and administrative staff meetings;
- E. A current copy of these regulations;
- F. Reports of inspections, reviews, and corrective actions taken related to licensure; and
- G. Contracts and agreements to which the facility is a party.

SECTION 305. Personnel

Qualified personnel shall be employed in sufficient numbers to carry out the functions of the facility. The licensee shall obtain written applications for employment from all employees. Such applications shall contain accurate information as to education, training, experience, health and personal background of each employee. All applications for licensed personnel shall contain the South Carolina license number and/or current renewal number, if applicable. All employees shall have a physical examination within one year prior to employment and a test for the hepatitis B surface antigen must be performed within one month prior to patient contact. (II)

A. All new employees shall have a tuberculin skin test within three months prior to patient contact unless a previously positive reaction can be documented. The intradermal (Mantoux) method, using five tuberculin units of stabilized purified protein derivative (PPD) is to be used. Employees with tuberculin test reactions of 10mm or more of induration should be referred for appropriate evaluation. The two-step procedure (one Mantoux test followed one week later by another) is advisable for initial testing for every new employee in order to establish a reliable baseline.

1. Employees with reactions of 10mm and over to the initial tuberculin test, those who are documented with previously positive reactions, those with newly-converted skin tests and those with symptoms suggestive of tuberculosis (e.g., cough, weight loss, night sweats, or fever, etc.) regardless of skin test status, shall be given a chest radiograph to determine whether tuberculosis disease is present. If tuberculosis is diagnosed, appropriate treatment should be given and contacts examined.

2. There is no need to conduct initial or routine chest radiographs on employees with negative tuberculin tests who are asymptomatic.

3. Employees with negative tuberculin skin tests shall have an annual tuberculin skin test and, depending upon the test results, shall be followed as described in this regulation.

4. No employee who is a positive reactor to the skin test shall have patient contact until certified non-infectious by a physician.

5. New employees who have a history of tuberculosis disease shall be required to have certification by a licensed physician that they are not contagious.

6. Employees who are known or suspected to have tuberculosis shall be required to be evaluated by a licensed physician and will not be allowed to return to work until they have been declared noncontagious.

7. Preventive treatment of new positive reactors without disease should be an essential component of the infection control program. It should be considered for all infected employees who have patient contact, unless specifically contraindicated. Routine annual chest radiographs of positive reactors do little to prevent tuberculosis and therefore are not a substitute for preventive treatment. Employees who complete treatment, either for disease or infection, may be exempt from further routine chest radiographic screening unless they have symptoms of tuberculosis.

8. Post exposure skin tests should be provided for tuberculin negative employees within 12 weeks after termination of contact for any suspected exposure to a documented case of tuberculosis.

9. A person shall be designated at each facility to coordinate tuberculosis control activities.

B. Additional direct care personnel (R.N.'s, L.P.N.'s, or patient care technicians) shall be on duty to assure a ratio of 1 person to each 4 stations or fraction thereof. (I)

C. Each equipment technician must have successfully completed a training course and demonstrated competence in supervising and/or providing maintenance and/or repair for dialysis and other related equipment. The programs must contain at least the following subject content: (II)

1. Prevention of hepatitis via dialysis equipment;
2. The safety requirements of dialysate delivery systems;
3. Bacteriologic control;
4. Water quality standards;
5. Repair and maintenance of dialysis and other equipment.

D. Personnel Records: A personnel record folder shall be maintained for each employee. The folder shall contain history and physicals, laboratory test results, resumes of training and experience, and current job description that reflects the employee's responsibilities and work assignments, orientation and periodic evaluations.

E. Job Descriptions:

1. Written job descriptions which adequately describe the duties of every position shall be maintained.
2. Each job description shall include: position, title, authority, specific responsibilities and minimum qualifications.
3. Job descriptions shall be given to each employee when assigned to the position and when revised. The job description shall be reviewed jointly by the employee and supervisor annually with signatures and date of review.

F. Orientation: (II)

1. Each facility shall have and execute a written orientation program to familiarize each new employee with the facility, its policies and job responsibilities.
2. For direct patient care personnel, the program shall contain at least the following subject content:

- a. Fluid and electrolyte balance;
- b. Kidney disease and treatment;
- c. Dietary management;
- d. Principles of dialysis;
- e. Dialysis technology;
- f. Venipuncture technique;
- g. Care of dialysis patient;
- h. Prevention of hepatitis and other infectious diseases.

G. Continuing education in ESRD care shall be provided to all non-clerical employees at least quarterly. Inservice training may be provided by qualified facility staff.

H. The physician-director shall certify that each direct care person has completed the appropriate orientation and has demonstrated competence in the technical areas of employment. The physician-director shall assure that each direct care person remain so competent.

SECTION 306. Medical Staff

A. If more than one physician practices in a facility, they shall be organized as a medical staff with appropriate bylaws approved by the governing body. The medical staff shall meet at least quarterly and minutes shall be maintained of such meetings.

B. The governing body shall designate a qualified physician as director of the ESRD services. The appointment shall be made upon the recommendation of the facility's organized medical staff, if there is one. The physician-director shall be responsible for the execution of patient care policies and medical staff bylaws and rules and regulations. (II)

C. A qualified nephrologist or licensed physician with demonstrated experience in the care of patients with end stage renal disease shall be on call and physically available to patients within a reasonable time. (I)

SECTION 307. Transfer Agreement

Each renal dialysis facility shall have in effect a transfer agreement with one or more hospitals, for the provision of inpatient care and other hospital services. The transfer agreement shall provide the basis for effective working relationships under which inpatient hospital care or other hospital services are promptly available to the dialysis facility's patients when needed. The dialysis facility shall have in its files documentation from the hospital to the effect that patients from the dialysis facility will be accepted and treated in emergencies. There shall be reasonable assurances that:

A. Transfer or referral of patients will be effected between the hospital and the dialysis facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission;

B. There shall be interchange, within one working day, of medical and other information necessary or useful in the care and treatment of patients transferred to a hospital or any other inpatient medical facility, or to another ESRD facility;

C. Security and accountability are assured for patient's personal effects.

SECTION 308. Rights of Patients

The governing body of the facility shall adopt written policies regarding the rights and responsibilities of patients and, through the administrator, shall be responsible for development of and adherence to procedures implementing such policies. These policies and procedures shall be made available to patients and any guardians, next of kin, sponsoring agency(ies), representative payees and to the public. The staff of the facility shall be trained and involved in the execution of such policies and procedures. (II)

A. The patients' rights policies and procedures shall ensure that all patients in the facility are:

1. Fully informed of these rights and responsibilities, and of all rules and regulations governing patient conduct and responsibilities;

2. Fully informed of services available in the facility and of related charges;

3. Informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records);

4. Afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research;

5. Be transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees and given notice to ensure orderly transfer or discharge; and

6. Treated with consideration, respect and full recognition of their individuality and personal needs, including the need for privacy in treatment.

B. The facility shall have written documentation by the patient that he/she has had his/her rights explained.

SECTION 309. Disaster Preparedness (II)

A. The facility shall have a posted plan for evacuation of patients, staff, and visitors in case of fire or other emergency.

B. Fire Drills:

1. At least one drill shall be held every three months to familiarize all employees with the drill procedure. Reports of the drills shall be maintained. Staff and patient participation shall be documented.

2. Upon identification of procedural problems with regard to the drills, records shall show that corrective action has been taken.

SECTION 310. Incident and Accident Reports

A record of each accident or incident occurring in the facility, including medication errors and adverse drug reactions shall be prepared immediately. Accidents resulting in serious injury or death shall be reported, in writing, to the licensing agency within 10 days of the occurrence. (II)

Accidents and incidents that must be recorded include but are not limited to:

1. Those leading to hospitalization;
2. Those leading to death;
3. Use of wrong dialyzer on patient;
4. Blood spills of more than 75 ml.;
5. Hemolytic transfusion reactions;
6. Reactions to dialyzers.

CHAPTER 4 Professional Care

SECTION 401. Patient Care and Professional Services

Written patient care policies relating to all areas of facility care shall be developed by the physician-director or medical staff and shall be approved by the governing body. They shall be reviewed at least yearly by a committee composed of a physician, RN, dietitian and social worker. Policy shall provide that the hours of dialysis shall be scheduled for patient convenience whenever feasible or possible. Policies shall discuss care of patients in medical emergencies, the kinds of emergencies they can handle, and when the patient must seek referral. Every patient shall be under the care of a physician. Patients shall be under the care of a physician. Patients shall be instructed in procedures to follow during medical emergencies which might arise during hours when they are inside/outside the facility. (II)

SECTION 402. Patient Care Plans

There shall be short-term and long-term care plans for each patient, developed by the professional team to ensure appropriate modality of care. The short-term and long-term care plans shall be developed within the first month of care. Such plans shall be based on the nature of the patient's needs based on prior medical workup.

A. The short-term care plan shall reflect medical, psychological, social, and dietary needs, and stability of patients. It shall be reviewed at least monthly on unstable patients, every six months on stable patients and revised as necessary. There shall be documentation of patient or legal guardian involvement in the development of the short-term care plan with the professional team.

B. The long-term care plan shall be reviewed at least annually and include:

1. Diagnosis;
2. Type of treatment (hemodialysis, CAPD, CCPD, self dialysis);
3. Medical plan for next year; and

4. Indication whether candidate for transplantation or home dialysis.

C. There shall be at least monthly dietitian progress notes and at least quarterly social worker notes.

SECTION 403. Medical Records

A. Medical Record System:

1. The facility shall maintain a medical record system designed to provide readily available information on each patient. The medical record system shall be under the supervision of a designated, qualified person. A member of the staff shall be designated to serve as supervisor of medical records services. If not a Registered Records Administrator (RRA) or Accredited Records Technician (ART), the staff member must receive consultation from RRA or ART. (II)

2. The medical records shall be completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information. All information shall be centralized in the patient's medical record. (II)

3. The facility shall maintain adequate facilities, equipment and space for record processing and statistical information. (II)

B. Medical Record Contents - Current medical records shall contain:

1. Face sheet

- a. Identification data (name, DOB, sex),
- b. Diagnosis,
- c. Doctor's name and phone number,
- d. Family member to be contacted in case of emergency and phone number,
- e. Patient's address and phone number,
- f. Date of admission;

2. Doctor's orders for at least one year. Standing orders shall be updated on an annual basis;

3. Documentation of physician's visit, at least weekly, by either progress note or run (flow) sheet for at least one year (at least one month of the most current run sheets must be contained in the active file);

4. Lab and x-ray reports;

5. Annual history and physical;

6. Social worker and dietary initial assessments, updates and progress notes for one year updates;

7. Miscellaneous consultations, hospitalizations;

8. Long-term care plan updated annually;
9. Current short-term care plan;
10. Nurses' progress notes each time of dialysis for one month;
11. Nurse's initial admission assessment;
12. Signed consent forms.

C. Medical records shall be completed within 30 days after discharge.

D. The administrator shall be responsible for safeguarding information in the medical record against loss, tampering or use by unauthorized persons.

E. Medical records shall be the property of the facility and shall not be removed from the premises wherein they are filed except by subpoena, court order or for valid medical reasons.

F. The length of time that medical records are to be retained is dependent upon the need for their use in continuing patient care and for legal, research or educational purposes. This length of time shall be not less than 10 years.

G. Should a facility cease operation, there shall be an arrangement for preservation of records to insure compliance with these regulations. The Department shall be notified, in writing, concerning the arrangements.

SECTION 404. Nursing Services

Each facility shall have the following minimum staffing to provide services: (I)

1. A registered nurse shall serve as the director of nursing. The director must have at least 18 months of experience in clinical nursing with at least six months experience in care of patients with ESRD.
2. A registered nurse who shall serve as charge nurse.
3. At least one registered nurse shall be on duty during each patient shift for each 10 stations or portion thereof. The charge nurse may serve in this capacity.

SECTION 405. Pharmaceutical Services

Pharmaceutical services shall be provided in accordance with accepted professional principles and federal, state and local laws and regulations.

A. Emergency Drugs:

1. Emergency Kit or Emergency Drugs. Each renal dialysis facility shall maintain, upon the advice and written approval of the physician-director, an emergency kit or stock supply of drugs and medicines for the use of the physician in treating the emergency needs of his patient. This kit or medicine shall be stored in such a manner as to prohibit its access by unauthorized personnel. If an emergency cart is utilized, a listing of contents by drawer shall be placed on the emergency cart to allow quick retrieval. Contents shall correspond with the inventory list. (I)

2. Drug Reference Sources. Each renal dialysis facility shall maintain reference sources for identifying and describing drugs and medicines. (II)

B.Administering Drugs and Medicines. Drugs and medicines shall not be administered to individual patients or to anyone within or outside the facility unless ordered by a physician duly licensed to prescribe drugs. Such orders shall be in writing and signed personally by the physician who prescribes the drug or medicine. All verbal or telephone orders shall be received by a registered nurse, licensed practical nurse, or a physician and shall be reduced to writing on the physician's order sheet with an indication as to the prescribing physician and who wrote the order. Telephone or verbal orders shall be signed and dated by the prescribing physician or designated physician(s) within 72 hours (a list of designated physicians shall be available at the facility). (I)

C.Medicine Storage. Medicines and drugs maintained in the facility for daily administration shall be properly stored and safeguarded in enclosures of sufficient size and which are not accessible to unauthorized persons. Refrigerators used for storage of medications shall maintain an appropriate temperature as determined by the requirements established on the label of medications. A thermometer accurate to ± 3 degrees shall be maintained in these refrigerators. Only authorized personnel shall have access to storage enclosures. Narcotics and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable state and federal laws. (I)

D.Medicine Preparation Area. Medicines and drugs shall be prepared for administration in an area which contains a counter and a sink. This area shall be located in such a manner to prevent contaminations of medicines being prepared for administration. (II)

E.Narcotic Permit. If a stock of controlled drugs is to be maintained, the facility may use the medical director's license for narcotics or procure a controlled drug permit from the S.C. Bureau of Drug Control and the Federal Drug Enforcement Agency. The permits shall be readily retrievable. (I)

F.Records. Records shall be kept of all stock supplies of controlled substances giving an accounting of all items received and/or administered. (I)

G.Poisonous Substances. All poisonous substances must be plainly labeled and kept in a cabinet or closet separate from medicines and drugs to be prepared for administration. (I)

H.Review of Medications. A physician, pharmacist or registered nurse shall review at least monthly all medications prescribed by the facility's physician for each patient, for potential adverse reactions, allergies, interactions, etc. (II)

SECTION 406. Dietary Services

All dietary consultation provided shall be under the supervision of a registered dietitian. Each patient shall be evaluated as to his/her nutritional needs by the attending physician and a dietitian. The dietitian in consultation with the physician shall be responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets. Each facility shall employ or contract with a dietitian(s) to provide for the dietary needs of each patient. The contractual hours shall be sufficient and agreed upon by the medical director and the dietitian to carry out these functions. (II)

SECTION 407. Laboratory Services (II)

A.Laboratory services shall be provided under contract to meet the needs of the patient except that hematocrits, clotting times and blood glucoses, which the facility uses to monitor its patients, may be done by the dialysis facility's staff, who are qualified by education and experience to perform such duties under the direction of a physician.

B.Controls. There shall be a quarterly constant packing time performed on all centrifuges used for hematocrits. Records of performed CPT shall be maintained.

C.Maintenance of Equipment. Each piece of equipment used to perform laboratory procedures shall be entered in the facility's preventive maintenance program.

D.Administration of Blood. If a facility administers blood to patients, the following must be complied with:

1. Blood must be transported from the laboratory processing the blood to the facility in a container that will ensure maintenance of a temperature of 1 to 10 degrees centigrade. Temperature must be recorded upon arrival.

2. If blood is not administered immediately upon arrival, it must be stored in a refrigerator at 1-6 degrees centigrade. The temperature of the refrigerator must be monitored and recorded.

E. All laboratory supplies shall be monitored for expiration dates, if applicable.

SECTION 408. Social Services

Social services shall be provided to patients and their families and shall be directed at supporting and maximizing the social functioning and adjustment of the patient. The social worker shall be responsible for conducting psycho-social evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psycho-social needs, providing case work and group work services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them. Each facility shall employ or contract with a social worker and adequate number(s) of qualified assistant(s) to meet the social needs of patients. (II)

SECTION 409. Infection Control

A.The facility shall have an infection control committee or any other appropriate committee composed of at least the administrator, a physician and a registered nurse which shall be responsible for writing and enforcing policies and procedures for preventing and controlling hepatitis and other infections. The policies and procedures shall include but not be limited to: (II)

1. Appropriate procedures for prevention of hepatitis and other infectious diseases, to include the utilization of universal precautions for prevention of transmission of bloodborne pathogens currently recommended by the Centers for Disease Control;

2. Appropriate procedures for surveillance and reporting of infections to include infection rates;

3. Housekeeping;

4. Handling and disposal of waste and contaminants;

5. Sterilization and disinfection of equipment;

6. Prevention of contamination by blood and other body fluids of units outside of the dialysis and dialyzer reprocessing areas including toilet facilities, staff lounge, etc.;

7. Protection of patient clothing during the time when blood lines are opened or needles inserted or withdrawn; and

8. Investigation of infections.

B. Reportable Diseases: All cases of diseases which are required to be reported in accordance with DHEC Regulation 61-20, Communicable Diseases, and any occurrences such as epidemic outbreaks or poisonings or other unusual occurrence, which threatens the welfare, safety or health of patients or personnel, shall be reported immediately to the local health director and to the Office of Health Licensing of the Department. (II)

C. Reports of infections such as abscesses, septicemia, hepatitis or other communicable diseases observed during admission or follow-up (or return) visit of the patient shall be made and kept as a part of the patient's medical files. Efforts shall be made to determine the origin of any such infection and if the dialysis procedure was found to be related to acquiring the infection, remedial action shall be taken to prevent recurrence. (II)

D. Hepatitis Surveillance: Hepatitis testing: Candidates for dialysis shall be screened for the hepatitis B surface antigen (HBsAg) within one (1) month before or at the time they enter the unit in order to determine their serologic status for surveillance purposes. All potential employees shall be screened for HBsAg prior to patient contact. This initial screening determines the individual's serologic status for surveillance purposes. Thereafter, routine serologic testing to monitor for hepatitis B infection shall be conducted in accordance with the following schedule: (I)

1. If Unvaccinated:

a. "Susceptible" (When individual is HBsAg and HBsAb-negative):

(1) For HbsAg, test patients monthly and staff semi-annually.

(2) For HbsAb, test patients and staff semi-annually.

b. "Infected" (When individual is HbsAg-positive):

(1) Test patients and staff for HBsAg, HBsAb, and HBcAb monthly for six months, then annually.

(2) If still positive, conduct annual HBsAg. If individual reverts to negative HBsAg, test HBsAb & HBcAg annually or one time which indicates "immune".

c. "Immune" (When individual is HBsAb-positive): Test patients and staff for HBsAb once to confirm status, then follow up every three years.

2. If Vaccinated:

a. "Immune" (When individual is HBsAb-positive): Test patients and staff for HBsAb once to confirm status, then follow up every three years.

b. "Low Level Immunity" or Negative (non-responder): Test patients and staff for HBsAb once to confirm status, then follow up every three years.

E. Isolation Facilities: (II) A separate isolation dialysis room shall be provided in all facilities accepting hepatitis B surface antigen positive patients.

F. Linens: (II)

1. All reusable linens, including those used as sterilizing wrappers, must be laundered before re-use.

2. Clean linens shall be handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

3. The facility shall have available at all times a quantity of linen essential for proper care and comfort of patients.

4. Used linens shall be kept in closed and covered containers while being stored or transported.

G. A sharp's disposal system shall be utilized and appropriately covered. (II)

H. Paper towels or air hand dryers and soap dispensers with soap must be provided at all lavatories in the facility. (II)

SECTION 410. Toxic and Hazardous Substances

The facility shall have policies and procedures for dealing with toxic and hazardous substances. Such policies and procedures shall conform to current Occupational Safety and Health Administration standards regarding formaldehyde, renalin or any other sterilizing agents. (II)

A. Procedures shall be developed to cover at a minimum:

1. Formaldehyde vapor concentration;

2. Fire prevention;

3. Solution exposure;

4. Large and small leaks from machines;

5. Large and small spills; and

6. Solution contact with eyes, skin and/or clothing (appropriate eyewash stations shall be provided in all facilities).

B. Routine monitoring of vapor concentration shall be conducted and recorded in writing in accordance with current OSHA guidelines.

SECTION 411. Home Dialysis (Self-Dialysis)

If the facility provides self-dialysis training, such training shall be provided by a registered nurse, who has had at least 12 months experience in dialysis. The facility shall provide directly or under arrangement the following services: (II)

A.Hemodialysis:

1. Surveillance of the patient's home adaptation, including provisions for visits to the home or the facility;
2. Consultation for the patient with a qualified social worker and a qualified dietitian;
3. A record keeping system which assures continuity of care;
4. Installation and maintenance of equipment;
5. Testing and appropriate treatment of the water; and
6. Ordering of supplies on an ongoing basis.

B.Continuous Ambulatory Peritoneal Dialysis (CAPD). Items 2,3, and 6 of paragraph "A" above must be provided.

C.Continuous Cycling Peritoneal Dialysis (CCPD). Items 1,2,3,4 and 6 of paragraph "A" above must be provided.

PART II Physical Plant

CHAPTER 20 Design and Construction

SECTION 2001. General

Every facility must be planned, designed and equipped to provide adequate facilities for the care and comfort of each patient.

SECTION 2002. Local and State Codes and Standards

Facilities shall substantially comply with pertinent local and state laws, codes, ordinances and standards with reference to design and construction. No facility will be licensed unless the Department has assurance that responsible local officials sanction the licensing of the facility. The Department uses as its basic codes the Standard Building Code, the Standard Plumbing Code, the Standard Mechanical Code, and the National Electrical Code. Buildings designed in accordance with the above mentioned codes will be acceptable to the Department, provided, however, that the minimum requirements as set forth in these standards are met. (II)

SECTION 2003. Submission of Plans and Specifications

1. New Buildings, Additions or Major Alterations to Existing Buildings: When construction is contemplated either for new buildings, additions or major alterations to existing buildings, plans and specifications shall be submitted to the Department for review. Such plans and specifications shall be prepared by an architect registered in the State of South Carolina and shall bear his/her seal. These

submissions shall be made in at least two stages: preliminary and final. All plans shall be drawn to scale with the title and date shown thereon. Construction work shall not be started until approval of the final drawings or written permission has been received from the Department. Any construction changes from the approved documents shall have approval from the Department. (II)

A. Preliminary submission shall include the following:

1. Plot plan showing size and shape of entire site; orientation and location of proposed building; location and description of any existing structures, adjacent streets, highways, sidewalks, railroads, et cetera, properly designated; size, characteristics and location of all existing public utilities, including information concerning water supply available for fire protection.

2. Floor plans showing overall dimensions of buildings; locations, size and purpose of all rooms; location and size of doors, windows and other openings with swing of doors properly indicated; locations of smoke partitions and firewalls; location of stairs, elevators, dumbwaiters, vertical shafts and chimneys.

3. Outline specifications listing a general description of construction including interior finishes and mechanical systems.

B. Final submission shall include the following: Complete working drawings and contract specifications, including layouts for plumbing, air conditioning, ventilation and electrical work and complete fire protection layout.

C. In construction delayed for a period exceeding 12 months from the time of approval of final submission, a new evaluation and/or approval is required.

D. One complete set of as built drawings shall be filed with the Department.

2. Licensure of Existing Structures: When an existing structure is contemplated for licensure as a new facility or as an expansion to an existing facility, the following submittals shall be made to the Department: (II)

(All plans shall be neatly prepared and drawn to scale with the title and date shown thereon.)

A. Plot plan in accordance with Section 2003.1.A.1.

B. Floor plan(s) in accordance with Section 2003.1.A.2, including location of stations.

C. Description of construction including outside walls, partitions, floor, ceiling and roof. The method of heating and cooling shall also be included.

D. Report from the local Fire Marshal's Office stating that the facility meets their requirements for a renal dialysis facility. Any deficiencies noted on the report shall be corrected prior to issuance of a license by the Department.

3. Minor Alterations in Licensed Facilities: When alterations are contemplated that may affect life safety, preliminary drawings and specifications, accompanied by a narrative completely describing the proposed work, shall be submitted to the Department for review and approval to insure that the proposed alterations comply with current safety and building standards.

SECTION 2004. Location

A.Environment: Facilities shall be located in an environment that is conducive to the type of care and services provided.

B.Transportation: Facilities must be served by roads which are passable at all times and are adequate for the volume of expected traffic.

C.Parking: The facility shall have parking space to satisfy the minimum needs of patients, employees, staff and visitors.

D.Communications: A telephone must be provided on each floor used by patients and additional telephones or extensions must be provided, as required, to summon help in case of fire or other emergency. Pay station telephones are not acceptable for this purpose.

SECTION 2005. Physical Facilities

A.The dialysis unit(s) shall be separate from other activities and shall be located in an area free of traffic by non-unit staff or patients. (II)

B.The nursing station shall be located in an area which provides adequate visual surveillance of patients on dialysis machines. (I)

C.Treatment areas shall be designed and equipped to provide proper and safe treatment as well as privacy and comfort for patients. Sufficient space shall be provided to accommodate emergency equipment and staff to move freely to reach patients in emergencies. (I)

D.At least two acceptable exits shall be provided for each facility. (II)

E.If the facility is located on the ground floor there must be one exit to the outside for ambulance and/or handicapped use. (II)

F.If the dialysis units are located above ground floor, the facility must have an elevator sized to accommodate a stretcher. (II)

G.Dialysis units shall be at least three feet apart with cubicle curtains or other means to provide complete privacy for each patient as needed. (II)

H.All rooms shall open onto a corridor leading to exit and all corridors used by patients shall be at least four feet wide. (II)

I. Each dialysis unit shall contain a minimum of 90 square feet per station and be so arranged as to facilitate both routine and emergency care of the patients. (II)

J. A waiting room shall be provided with sufficient seating for patients and visitors.

K.Ample storage rooms shall be provided for supplies and equipment. At least ten square feet of floor space per unit shall be provided.

L. A clean work area that contains a work counter, handwashing sink, and storage facilities for the storage of clean and sterile supplies must be provided. (II)

M. A soiled work area that contains a work counter, handwashing sink, storage cabinets and waste receptacle shall be provided. (II)

N. Patient toilet facilities shall be provided.

O. A separate staff toilet and personal storage space shall be provided within the unit.

P. Separate storage space shall be provided for oxygen cylinders if a piped system is not provided. (II)

Q. A janitor's closet shall be provided adjacent to and for the exclusive use of the dialysis facility.

SECTION 2006. Maintenance

A facility's structure, its component parts, and all equipment such as elevators, furnaces and emergency lights, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed so as to allow sanitizing. (II)

SECTION 2007. Housekeeping (II)

A. General: A facility shall be kept clean and free from odors. Accumulated waste material must be removed daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings, woodwork, and windows. The premises must be kept free from rodent and insect infestation. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times. Cleaning materials and supplies shall be stored in a safe manner in a well-lighted closet. All harmful agents shall be locked in a closet or cabinet used for this purpose only.

B. Dialysis Station: Each unit shall be cleaned in accordance with established written procedures after each use.

SECTION 2008. Water Supply and Plumbing

A. Water Supply: Water shall be obtained from a community water system and shall be distributed to conveniently located taps and fixtures throughout the facility and shall be adequate in volume and pressure for all purposes. (II)

B. The dialysis facility shall enter into an agreement with the water district or similar authority whereby the facility is regularly notified of situations occurring outside the facility which may adversely impact water quality including but not limited to: (I)

1. Changes in treatment methods and source;
2. Municipal water treatment equipment failure;
3. Damage to the distribution system; and
4. Chemical spills.

C. Water used for dialysis purposes shall be analyzed for bacteriological quality at least monthly and chemical quality at least quarterly and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques. (I) Water used to prepare a dialysate shall not contain concentrations of elements or organisms in excess of those specified below:

<u>ELEMENTS</u>	<u>LIMIT IN MILLIGRAMS PER LITER</u>
Aluminum	.01
Arsenic	.005
Barium	.100
Cadmium	.001
Calcium	2.0
Chloramines	.001
Chlorine	.500
Chromium	.014
Copper	.100
Fluorides	.200
Lead	.005
Magnesium	4.0
Mercury	.0002
Nitrates (Nitrogen)	2.0
Potassium	8.0
Selenium	.090
Silver	.005
Sodium	70.0
Sulfates	100.0
Zinc	.100
Bacteria	200 colonies per milliliter

D.Plumbing: All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of the Standard Plumbing Code. All plumbing shall be installed in such a manner as to prevent back siphonage or cross-connections between potable and non-potable water supplies. (II)

SECTION 2009. Refuse and Waste Disposal (II)

A.Storage and Disposal: All garbage and refuse shall be stored in durable, nonabsorbent, rodent proof, closed containers. These containers shall be covered and stored outside. All solid waste shall be disposed of at sufficient frequencies in a manner so as not to create a rodent, insect or other vermin problem.

B.Cleaning: Immediately after emptying, containers for waste shall be cleaned.

SECTION 2010. Outside Areas

All outside areas, grounds and/or adjacent buildings shall be kept free of rubbish, grass, and weeds that may serve as a fire hazard or as a haven for roaches, rodents and other pests. Outside stairs, walkways, ramps and porches shall be maintained free from accumulations of water, ice, snow and other impediments.

CHAPTER 21 Fire Protection and Prevention

SECTION 2101. Fire Extinguishers, Standpipes, and Automatic Sprinklers

Fire-fighting equipment such as fire extinguishers, standpipes and automatic sprinklers shall be provided as required by the Standard Building Code. Extinguishers shall be sized, located, installed and maintained

in accordance with NFPA No. 10. Suitable fire extinguishers shall also be installed in all hazardous areas. Each facility shall conform with all state and local fire and safety provisions. (I)

SECTION 2102. Alarms

A manual fire alarm system in accordance with provisions of "Local Protective Signaling System," NFPA No. 72A, shall be provided. (I)

SECTION 2103. Gases

Gases (flammable and nonflammable) shall be handled and stored in accordance with the provisions of applicable NFPA codes. (I)

CHAPTER 22 Mechanical Requirements

SECTION 2201. Heating, Air Conditioning and Ventilation

Heating, air conditioning and ventilation systems shall be capable of maintaining comfortable temperatures. Workrooms and soiled utility areas must have exhaust of air to the outside. (II)

SECTION 2202. Emergency Electrical Power

The facility shall be equipped with an emergency power source. (I)

SECTION 2203. Lighting and Electrical Services

All electrical and other equipment used in the facility shall be maintained free of defects which could be a potential hazard to patients or personnel. There shall be sufficient safe lighting for individual activities, including suitable lighting for corridors and baths. Lighting in work area shall never be less than fifty foot-candles. (II)

SECTION 2301. Equipment Maintenance

A written preventive maintenance program for all equipment used in dialysis and related procedures including, but not limited to, all patient monitoring equipment, isolated electrical systems, conductive flooring, patient ground systems, and medical gas systems shall be developed and implemented. This equipment shall be checked and/or tested at such intervals to insure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance. (II)

CHAPTER 24 General

SECTION 2401. General

Conditions arising which have not been covered in these regulations shall be handled in accordance with the best practices as interpreted by the Department.

APPENDIX A

Prerequisites for Initial Licensure - Renal Dialysis Facility

Prior to admission of patients to, and issuance of a license for new facilities or additional station, the following actions must be accomplished:

1. The facility must be issued a Certificate of Need in accordance with DHEC Regulation 61-15.
2. Plans and construction must be approved by the Division of Health Facilities Construction, DHEC.
3. The facility shall submit a completed Application for License on forms which shall be furnished by the Office of Health Licensing. The following documents shall be submitted with the application:
 - a. Final construction approval of both water and wastewater systems by the appropriate District Environmental Quality Control Office of DHEC (Includes satisfactory laboratory reports of water samples taken by the local office of Environmental Quality Control).
 - b. Laboratory reports including chemical analysis and bacteriological culturing to assure water for dialysis conforms to the American National Standard for Hemodialysis Systems.
 - c. Approval from appropriate building official stating that all applicable local codes and ordinances have been complied with.
 1. If the facility is located within town or city limits, approval by the local fire chief stating that all applicable requirements have been met, or
 2. If the facility is located outside town or city limits, a written agreement with the nearest fire department that will provide protection and respond in case of fire at the facility.
 - d. Certification and laboratory test reports, provided by the manufacturer or supplier, that all carpeting purchased by the facility has been tested under
 1. ASTM E-84 and has a flame spread rating of not more than 75, or
 2. ASTM E-648 or NFPA No. 253 with a rating of not less than .45 watts/sq. cm.
 - e. Certification by the contractor that only the carpeting described in (d) above was installed in the facility.
 - f. Certification by the manufacturer or supplier that all drapes and cubicle curtains purchased by the facility are flame or fire resistant or retardant.
 - g. Certification by the owner or contractor that only materials described in (f) above were installed.
 - h. Certification by the manufacturer or supplier that all wall covering materials purchased by the facility are fire or flame resistant or retardant.
 - i. Certification by the owner or contractor that only the materials described in (h) above were installed.
 - j. Certification by the engineer that all fire alarm and smoke detection systems have been installed according to plans and specifications, have been tested and operate satisfactorily.

k. Certification by the contractor that the automatic sprinkler system, if applicable, has been completed and tested in accordance with the approved plans and specifications and NFPA No. 13.

l. Certification that all medical gas systems have been properly installed and tested.

m. For corporation-owned facilities, a list of all officers and their corporate titles.

4. Resumes for the persons in charge of the day-to-day operation of the facility and nursing services.

5. Resumes for the dietitian and social worker.

6. Required personnel must be employed, available, trained and capable of performing their duties.

7. The Office of Health Licensing shall inspect the facility and require compliance with these regulations.

8. The facility must pay the required licensing fee.